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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,108	09/25/2003	Homme W. Hellinga	180/106	8184

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,108	HELLINGA ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31 and 42 are drawn an isolated GB1 polypeptide and a method of preparation, classified in class 424, subclass 93.42.

II. Claims 32-41 are drawn to an isolated nucleic acid molecule and recombinant host cell, classified in class ~~514~~ 536, subclass ~~44~~ 23.1.

III. Claims 43-46 are drawn to a method of purification, classified in class 435, subclass 235.1.

IV. Claims 47-51 are drawn to a method of purification comprising a contact step; a collection step and an elution step, classified in class 435, subclass 239.

V. Claims 52-56 are drawn to a method of detection, classified in class 435, subclass 7.92.

2. The inventions are distinct, each from the other because of the following reasons.

A) Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptide and method of preparation of Group I has different effects, function and mode of operation as compared to the invention of Group II. Thus the inventions of I and II are related as different products. Polypeptides which are comprised of amino acids and polynucleotides which are composed of purines and

pyrimidine units are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependant upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The information provided by the polynucleotide of group II can be used to make a materially different polypeptide than that of group II. Furthermore, the information provided by the polynucleotide of group II can be used to make a materially different polypeptide than that of group I. For example, a nucleic acid which hybridizes, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with the polypeptide of group I. In addition, while a polypeptide of group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of group II, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to

the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides that would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above. As such, it would be burdensome to search the inventions of groups I and II together.

B) Inventions I and any of groups III, IV or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inventions of Groups III and IV are drawn to the purification of antibody fragments while group V is drawn to the detection of antibodies or their fragments. Group I is drawn to a GB1 polypeptide, therefore the processes are used with different products and are not useable together. In the instant case the polypeptide of group I can be used to make antibodies as opposed to being used in methods of purification or detection.

Searching the inventions of Groups I and III, IV or V together would impose serious search burden. The inventions of Groups I and III, IV or V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of purification or detection are not coextensive. Group I encompasses molecules which are claimed in terms of exhibiting binding activity, which are not required for the search of Groups III, IV or V. In contrast, the search for group V would require a text search for the method of detection. Thus the prior art could teach a polypeptide that would not necessarily be applicable to the method of purification or detection. Moreover, even if the polypeptide product were known, the method of purification or detection using the product may be novel and unobvious in view of the preamble or active steps.

C) Inventions II and III, IV or V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inventions of Groups III and IV are drawn to the purification of antibody fragments while group V is drawn to a method for the detection of antibodies or their fragments. Group II is drawn to a nucleic acid molecule and recombinant host cells, thus the product is used with different processes and not useable with any of Group III, IV or V. In the instant case

the isolated nucleic acid of group II can be used to encode a polypeptide as opposed to being used in methods of purification or detection.

Searching the inventions of Groups II and III, IV or V together would impose serious search burden. The inventions of Groups II and III, IV or V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of purification or detection are not coextensive. Group II encompasses isolated nucleic acid molecules which are claimed in terms of binding a Fab fragment, however said activity is not required for the search of Groups III, IV or V. In contrast, the search for group V would require a text search for the method of detection. Therefore the prior art likely teaches isolated nucleic acid molecules that would not necessarily be applicable to the method of purification or detection. Moreover, even if the isolated nucleic acid product were known, the method of purification or detection using the product may be novel and unobvious in view of the preamble or active steps.

D) Inventions III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are the method of purification of antibody fragments and the method of detection of antibodies and/or antibody fragments. There are different steps required for the practice of the different methods,

such as the detection step of Group IV. Therefore the inventions of Group III and IV have different modes of operation, functions and effects.

Furthermore the distinct steps and products require separate and distinct searches. The inventions of Groups III, IV and V have a separate status in the art as shown by their different classification. As such, it would be burdensome to search the inventions of groups III, IV and V together. Furthermore, a search for the invention of the three groups would not be coextensive because a search indicating the process of one is novel or unobvious would not extend to a holding that the process of the other is novel or unobvious. Because of the different classification of each group based upon the distinct method steps, a serious burden is imposed on the examiner to perform a complete search of the defined areas in both the patent and non-patent literature. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden on the examination of this application.

3. Claims 7, 33 and 34 are drawn to a plurality of disclosed patentably distinct inventions comprising SEQ ID NO's 6, 20, 22 and 24 in claim 7; SEQ ID NO's 6, 8, 10, 12, 14, 16, 18, 20, 22 and 24 in claim 33; and SEQ ID NO's 5,7,9, 11, 13, 15, 17, 19, 21 and 23 in claim 34. The separate polypeptides and polynucleotides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers and having different binding epitopes for unique diverse antibodies as defined in the disclosure. **Therefore, each disclosed patentably distinct polypeptide or polynucleotide is considered a separate invention.** The inventions are distinct, each

from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: these products appear to constitute patentably distinct inventions for the following reasons: the numbered groups are directed polypeptide and polynucleotide sequences comprising SEQ ID NO: 5-24 which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct amino acid or nucleic acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-V, restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations

of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 13, 2005

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